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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROSS E. MANTLE

Appeal 2009-006617
Application 10/523,857
Technology Center 3700

Decided: May 6, 2010

Before LINDA E. HORNER, MICHAEL W. O'NEILL, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

SILVERBERG, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Ross E. Mantle (Appellant) seeks our review under 35 U.S.C. § 134 of the final rejection of claims 1-13 and 18-37. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF DECISION

We AFFIRM-IN-PART.

THE INVENTION

Appellant's claimed invention is directed to processes and devices for automated liquid recirculation to and from a body cavity (Spec. 1: 7-11 and Spec. 7: 15-30).

Claims 1, 18, 28 and 32, reproduced below, are representative of the subject matter on appeal.

1. Apparatus for modulating the temperature and pressure within a body cavity by means of recirculation of a biological or biocompatible liquid within the cavity, but outside of blood vessels, which comprises: (a) first pump means for infusing liquid at a controlled temperature and flow rate into the cavity; (b) means for monitoring the temperature within the cavity; (c) means for monitoring the pressure within the cavity; and (d) second pump means for withdrawing liquid at a controlled flow rate from the cavity.

18. Apparatus for modulating introduction and removal of a liquid within a cavity of a patient's body, the cavity comprising a cavity outside of blood vessels, the apparatus comprising:
a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity;
one or more sensors positionable in the patient's body so as to sense a condition of liquid in the cavity; and
a controlled pumping system operatively coupled to both the catheter and the one or more sensors, the controlled pumping system configured

to control introduction and removal of liquid from the cavity so as to maintain a selected liquid condition value.

28. A feedback-controlled apparatus for introduction and removal of a liquid within a cavity of a patient's body, the cavity comprising a cavity outside of blood vessels, the apparatus comprising:

- a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity;

- one or more sensors positionable so as to sense a biological parameter of a patient's body;
- and

- a controlled pumping system operatively coupled to both the catheter and the one or more sensors, the controlled pumping system configured to modulate a property of the liquid in response to signals received from the one or more sensors and to maintain the biological parameter of the patient's body within a selected range.

32. A method of maintaining a liquid condition parameter within a body cavity other than a blood vessel within a patient's body, the method comprising:

- pumping liquid into the cavity;
- pumping liquid out of the cavity;
- monitoring a parameter of liquid within the cavity from a sensor disposed within the patient's body; and

- controlling at least one of liquid temperature, liquid pressure, and liquid flow rate in response to a liquid condition value measured in the monitoring step.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Leonard	US 3,927,980	Dec. 23, 1975
Osterholm	US 4,450,841	May 29, 1984
Gutierrez-Collazo	US 5,562,821	Oct. 8, 1996
Ginsburg	US 6,497,721 B2	Dec. 24, 2002
Maginot	US 6,743,218 B2	Jun. 1, 2004

The following rejections by the Examiner are before us for review:

1. Claims 1-9, 11-13, 18-23¹, 25-30, 32-34 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Osterholm in view of Leonard and Ginsburg.
2. Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Osterholm in view of Leonard and Ginsburg, and further in view of Gutierrez-Collazo.
3. Claims 24, 31, 35 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Osterholm in view of Leonard and Ginsburg, and further in view of Maginot.

¹ Claims 20, 25 and 26, which are part of this appeal (App. Br. 2), were not listed in the Grounds of Rejection section of the Examiner's Answer, as being rejected over the prior art of record (Ans. 3). However, a discussion of the rejections of claims 20, 25 and 26 were included in paragraphs [13] and [14], respectively (Ans. 8-9), which are subparagraphs under paragraph 2 containing the rejection of claim 18 (Ans. 3). Claims 20 and 25 depend from claim 18, and claim 26 depends from claim 25. Appellant acknowledges the Examiner's intentions to reject claims 20, 25, and 26. *See* App. Br. 4, fn. 2. Accordingly, we will consider claims 20, 25 and 26 in this appeal as having been rejected along with claim 18 over Osterholm in view of Leonard and Ginsburg.

ISSUES

The issues before us are:

(1) whether the Examiner erred in finding that the combined teachings of Osterholm, Leonard and Ginsburg would have led a person having ordinary skill in the art to (a) means to monitor the temperature and pressure within a cavity, and (b) a pump to withdraw liquid out of space from which it was injected as called for in claim 1 (Reply Br. 2-3, App. Br. 6-7);

(2) whether the Examiner erred in finding that Osterholm describes “a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity” as called for in independent claims 18 and 28 (App. Br. 7-8); and

(3) whether the Examiner erred in finding that the combined teachings of Osterholm, Leonard and Ginsburg would have led a person having ordinary skill in the art to the steps of “monitoring a parameter of liquid within the cavity from a sensor disposed within the patient's body; and controlling at least one of liquid temperature, liquid pressure, and liquid flow rate in response to a liquid condition value measured in the monitoring step,” as called for in claim 32 (App. Br. 8).

FINDINGS OF FACT

We find that the following enumerated findings are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

The Examiner's Findings

1. The Examiner finds that Osterholm describes all of the limitations called for in independent claims 1, 18, 28 and 32, except that Osterholm does not describe “that the monitoring means monitor temperature and pressure within the cavity, nor does it teach a second pumping means for withdrawing liquid at a controlled rate from the cavity,” as called for in claim 1 (Ans. 4).
2. The Examiner finds that Osterholm describes an apparatus comprising a first pump means 18 for infusing a liquid at a controlled temperature and flow rate into a cavity; means for monitoring the temperature of the fluid 14, 40; and means for monitoring the pressure of the fluid 18, 38 (Ans. 4).
3. The Examiner finds that Osterholm’s means for monitoring temperature and pressure is done within a storage chamber and not within the body (Ans. 5).
4. The Examiner finds, regarding claims 18 and 28, that “Osterholm clearly teaches a catheter (i.e. fluid flow line) that is adapted to introduce and remove fluid from the cavity.” (Ans. 12-13).
5. The Examiner finds that Leonard describes “an extracorporeal system comprising a first pump 36 capable of infusing a liquid and a second pump 40 capable of withdrawing a liquid at a controlled flow rate (see Figure 1).” (emphasis added) (Ans. 4).
6. The Examiner finds that “Leonard generally teaches that the use of two pumps (one inlet, one outlet) to control the flow of fluid through a fluid system allows for improved control over pressure and flow rate.” (Answer 11-12).

7. The Examiner finds that “Ginsburg generally teaches the use of body-implanted sensors to monitor temperature and pressure within a cavity (Column 5, Lines 58-65, Column 14, Lines 49-59, and Abstract).” (Ans. 12).

The Board's Findings

8. Osterholm describes withdrawing fluid through a catheter 30 from the cisterna magna 24, continuously monitoring various chemical and physical characteristics of the fluid (e.g., temperature, oxygenation, pressure) by an output monitor (fig. 1), sterilizing and reconstituting the fluid at step 32, adjusting the temperature to a preselected temperature 14, 40, controlling the oxygenation 16, 36 and adjusting the pressure 18, 38, (col. 13, l. 30-col. 14, l. 54 and col. 15, ll. 3-21 and fig. 1).
9. Osterholm describes injecting the fluid through an injection catheter 120 to the lateral ventricle of the human brain 24 (col. 12, ll. 30-32 and figs. 1, 13).
10. Osterholm describes using a delivery pump 107 for establishing the final injection rate (col. 12, l. 13 and fig. 13).
11. In Osterholm, the lateral ventricle 20 of the human brain and the cisterna magna 24 comprise a cavity as a person having ordinary skill in the art would understand because the ventricle is in fluid communication with other portions of the cerebrospinal pathway and they collectively form a hollow space.² (See col. 11, ll. 15-35).
12. Leonard describes using two pumps, a first arterial pump 36 and a second venous pump 40, to aid in protecting an extracorporeal

² See STEDMAN'S MEDICAL DICTIONARY (27th ed. 2000).

oxygenator 20 and a heat exchanger 30 from overpressurization (col. 3, ll. 24-60 and fig. 1).

13. Ginsburg describes (1) that an aspect of the invention is to control the internal body temperature of a patient, and (2) that feedback from temperature sensors located within a patient's body allow for the control of the heat transfer from the catheter to automatically control the temperature of the patient or of the target region within the patient (Abstract).

14. Ginsburg describes that:

[t]he TE cooler and the pump are responsive to a controller unit 344. The control unit receives data input through electrical connections 345, 346, 347 to numerous sensors, for example body temperature sensors 348, 349 that may sense temperatures from a patient's ear . . . or other appropriate location as desired by the operator who places the sensors. Likewise, a sensor 350 may monitor the temperature of the heat exchange balloon, and *other sensors (not shown) may be provided as desired to monitor the blood temperature at the distal tip of the catheter, at the proximal tip of the catheter, or other desired location.*

(emphasis added) (col. 22, ll. 36-47 and fig. 16).

15. Additional findings as necessary appear in the Analysis portion of this opinion.

PRINCIPLES OF LAW

Obviousness

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 407 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”).

In *KSR*, the Supreme Court held that “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417.

In *KSR*, the Supreme Court stated that:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 418. The Court noted that “[t]o facilitate review, this analysis should be made explicit.” *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))

(“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)). However, “the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418.

In *KSR*, the Supreme Court stated that “[c]ommon sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. . . . A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 420-421.

ANALYSIS

Rejection of claims 1-9 and 11-13 over Osterholm, Leonard and Ginsburg; and the rejection of claim 10 over Osterholm, Leonard, Ginsburg and Gutierrez-Collazo

Appellant argues claims 1-9 and 11-13 as a group (App. Br. 5). As such, we select claim 1 as representative of the group, and claims 2-9 and 11-13 will stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii) (2009).

Claim 1

Appellant agrees with the Examiner’s finding that Osterholm does not describe (1) means to monitor the temperature and pressure within a cavity, and (2) a pump to withdraw liquid out of space from which it was injected as called for in claim 1. (*See* Fact 1).

Appellant contends, however, that Leonard does not describe injecting and withdrawing liquid from the same cavity as called for in claim 1 (App. Br. 5). Appellant contends that Ginsburg does not describe means for monitoring temperature and pressure within a cavity as called for in claim 1 (App. Br. 6). Appellant further contends that the combined teachings of Osterholm, Leonard and Ginsburg do not describe (1) means to monitor the temperature and pressure within a cavity, and (2) a pump to withdraw liquid out of space from which it was injected as called for in claim 1. (Reply Br. 2-3, App. Br. 6-7).

Appellant contends that the Examiner ignored the claim limitation “outside of blood vessels,” as set forth in the preamble of claim 1. (Reply Br. 2-3).

The Examiner found that Osterholm describes an apparatus comprising a first pump means 18 [*sic* 107] for infusing a liquid into a cavity; means for monitoring the temperature of the fluid 14, 40; and means for monitoring the pressure of the fluid 18, 38 (Fact 2), wherein the means for monitoring the temperature and pressure is done within a storage chamber and not within the body (Fact 3). (*See also* Facts 8-10).

The Examiner found that Leonard describes a first pump 36 capable of infusing a liquid and a second pump 40 capable of withdrawing a liquid (Fact 5), wherein the use of two pumps allows for improved control over the pressure of the liquid (Fact 6). In particular, Leonard’s two pumps 36, 40 aid in protecting an extracorporeal oxygenator 20 and a heat exchanger 30 from overpressurization (Fact 12).

The Examiner found that Ginsburg describes body-implanted sensors to monitor temperature and pressure within a cavity (Fact 7). The Examiner

concluded that Ginsburg's internal sensors would improve the accuracy of the monitoring of the temperature and the pressure (Fact 7).

In particular, Ginsburg describes controlling the internal body temperature of a patient, wherein feedback from temperature sensors located within a patient's body allow for the control of the heat transfer from the catheter to automatically control the temperature of the patient or of the target region within the patient (Fact 13, *see also* Fact 14).

Claim 1 calls for, *inter alia*, "(b) means for monitoring the temperature within the cavity; (c) means for monitoring the pressure within the cavity; and (d) second pump means for withdrawing liquid at a controlled flow rate from the cavity."

Claim 1 is drafted in such a manner that there is no interaction between the claimed elements. The recitation "but outside of blood vessels" is not limiting because the claimed apparatus is structurally complete within the claim body. *See, e.g., Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)(stating that a preamble is not limiting where a structurally complete apparatus is recited in the body of the claim and the preamble merely states an intended use of the apparatus). Therefore, we find that the combined teachings of the prior art need only describe the individual elements called for in claim 1 to render obvious the claimed invention. *See KSR*, 550 U.S. at 420-421.

We find that in Osterholm, the lateral ventricle 20 of the human brain and the cisterna magna 24 are a cavity as a person having ordinary skill in the art would understand that term (Fact 11).

While Osterholm describes using a pump 107 to inject the fluid into the body cavity, and describes injecting and withdrawing liquid from the

same cavity (Facts 8, 9), Osterholm does not describe using a pump to withdraw the fluid (Fact 1).

Leonard does not describe injecting and withdrawing liquid from the same cavity, but does describe using a first pump to withdraw fluid and a second pump to inject fluid to prevent overpressurization of an oxygenator 20 (Facts 5, 6, 12).

Monitoring and controlling the pressure of the fluid is a concern of Osterholm (Facts 2, 8).

Therefore, we agree with the Examiner's analysis and conclude that it would have been obvious to a person having ordinary skill in the art to combine the teachings of Osterholm, Leonard and Ginsburg by providing Osterholm with a second pump, that is, a pump to withdraw fluid from the body cavity as taught by Leonard at 40, and to internally monitor both the temperature and pressure as taught by Ginsburg.

We conclude that providing Osterholm with a pump to withdraw fluid from the body cavity would not be beyond the level of skill of an artisan in order to improve a similar device and to yield the predictable result of aiding in the protecting against overpressurization. *See id.* at 417.

Additionally, we conclude that providing Osterholm with internal sensors to measure the temperature and pressure of the fluid could have been reasonably predicted to yield the result of improving the accuracy of the monitoring of the temperature and pressure. *See id.*

Therefore, we conclude that the Examiner has not erred in rejecting claim 1 over Osterholm, Leonard and Ginsburg. Likewise, the Examiner has not erred in rejecting claims 2-9 and 11-13 which stand or fall with claim 1.

Claim 10

Appellant does not present any separate arguments for the patentability of dependent claim 10 apart from independent claim 1, other than Gutierrez-Collazo does not overcome the deficiencies of Osterholm, Leonard and Ginsburg (App. Br. 9).

Therefore, for the reasons set forth in our discussion of the rejection of independent claim 1, *supra*, we conclude that the Examiner has not erred in rejecting claim 10 over Osterholm, Leonard, Ginsburg, and Gutierrez-Collazo.

Rejection of claims 18-23 and 25-30 over Osterholm, Leonard and Ginsburg

Appellant contends that Osterholm does not describe “a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity” as called for in independent claims 18 and 28 (App. Br. 7-8).

The Examiner found that Osterholm clearly teaches a catheter that is adapted to introduce and remove fluid from the cavity (Fact 4).

Claims 18 and 28 call for, *inter alia*, a catheter configured for the introduction and removal of liquid from the cavity. As such, we construe that the claimed catheter is required to be able to both introduce and remove liquid.

Osterholm describes injecting fluid via a first catheter 120 and withdrawing fluid via a second catheter 30. (Facts 8-9). Therefore, Osterholm describes two different catheters for the introduction and removal of fluid.

Accordingly, Osterholm does not describe a catheter configured for the introduction and removal of liquid from the cavity as called for in independent claims 18 and 28.

The Examiner has not relied on either Leonard or Ginsburg for any teaching that would remedy this deficiency in Osterholm. (Ans. 3, 13).

Therefore, we conclude that the Examiner has erred in rejecting independent claims 18 and 28 over Osterholm, Leonard and Ginsburg. Likewise, the Examiner has erred in rejecting claims 19-23, 25-27, 29 and 30, which depend from claims 18 and 28, respectively.

Rejection of claims 32-34 and 37 over Osterholm, Leonard and Ginsburg

Appellant contends that the combined teachings of Osterholm, Leonard and Ginsburg do not describe the steps of “monitoring a parameter of liquid within the cavity from a sensor disposed within the patient's body; and controlling at least one of liquid temperature, liquid pressure, and liquid flow rate in response to a liquid condition value measured in the monitoring step,” as called for in claim 32 (App. Br. 8-9).

The Examiner found (1) that Osterholm describes monitoring pressure and temperature outside the body (Facts 1-3), and (2) that Ginsburg's body implanted sensors allow more accurate monitoring of the pressure in the body. (Fact 7).

The Examiner concluded that “the cited art reasonably suggests teh [sic the] device as claimed.” (Ans. 14).

We conclude that the Examiner's analysis is flawed. The Examiner's explanation of the rejection improperly sets forth a “reasonable suggestion” standard as the basis for a proper legal conclusion of obviousness. The

determination as to whether there was an apparent reason to combine the known elements of Osterholm and Ginsburg in the manner claimed requires an analysis regarding the teachings of Osterholm and Ginsburg, and the knowledge of a person having ordinary skill in the art. However, the Examiner has not provided an adequate analysis as to how the known elements of Osterholm and Ginsburg would be combined by a skilled artisan in the manner called for in independent claim 32. Further, the Examiner has not adequately articulated a rationale as to why a person having ordinary skill in the art would have combined the teachings of Osterholm and Ginsburg in the manner claimed. *See id.* at 418.

The Examiner has not relied on Leonard for any teaching that would remedy the deficiency in Osterholm and Ginsburg. (Ans. 3, 13).

Therefore, we conclude that the Examiner has erred in rejecting independent claims 32 over Osterholm, Leonard and Ginsburg. Likewise, the Examiner has erred in rejecting claims 33, 34 and 37, which depend from claim 32.

Rejection of claims 24, 31, 35 and 36 over Osterholm, Leonard, Ginsburg and Maginot

The Examiner has not relied on Maginot for any teaching that would remedy the deficiency in the combination of Osterholm, Leonard and Ginsburg (Ans. 10). We thus conclude that the Examiner also erred in rejecting claims 24, 31, 35 and 36 over Osterholm, Leonard, Ginsburg and Maginot.

CONCLUSIONS

The Examiner has not erred in finding that the combined teachings of Osterholm, Leonard and Ginsburg would have led a person having ordinary

skill in the art to (1) means to monitor the temperature and pressure within a cavity, and (2) a pump to withdraw liquid out of space from which it was injected as called for as called for in claim 1.

The Examiner has erred in finding that Osterholm describes “a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity” as called for in independent claims 18 and 28.

The Examiner has erred in finding that the combined teachings of Osterholm, Leonard and Ginsburg would have led a person having ordinary skill in the art to the steps of “monitoring a parameter of liquid within the cavity from a sensor disposed within the patient's body; and controlling at least one of liquid temperature, liquid pressure, and liquid flow rate in response to a liquid condition value measured in the monitoring step,” as called for in claim 32.

DECISION

The decision of the Examiner to reject claims 1-13 is affirmed. The decision of the Examiner to reject claims 18-37 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART

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